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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,696	03/17/2004	Cheryl Ann Janson	P50937C1	3958

7590 07/25/2006

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,696	JANSON ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-27 are pending in the application.

[2] Applicant's preliminary amendment to the specification, filed on 3/17/2004, is acknowledged.

[3] In response to this Office action, the status of priority application 09/980,945 should be updated in the continuing data in the first paragraph of the specification. According to USPTO records, application 09/980,945 is now abandoned.

[4] It is noted that in the transmittal form filed on 3/17/2004, it is requested that the instant application use the computer readable form of parent application 09/980,945. However, the examiner can find no statement that the paper copy of the sequence listing filed on 3/17/2004 is identical to the sequence listing in computer readable form in application 09/980,945. In order to perfect sequence compliance, applicant is requested to provide such statement in response to this Office action.

Election/Restrictions

[5] Claims 19-21 link(s) inventions III and IV. According to the specification, Figure 1 provides the structural coordinates for an *E. coli* FabH dimer and Figure 2 provides the structural coordinates for an *E. coli* FabH monomer in complex with acetyl-CoA (p. 2, bottom) and Tables I-II provide structural coordinates for the apo *E. coli* FabH structure in the active site and Table III provides structural coordinates for acetyl-CoA complex structure in the active site (pp. 7, 13, and 27). The restriction requirement between the

linked inventions is subject to the nonallowance of the linking claim(s), claims 19-21. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

[6] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a composition comprising an *E. coli* FabH in crystalline form, an *E. coli* FabH crystal, a selenomethionine mutant crystal of an *E. coli* FabH, and a FabH molecule, classified in class 435, subclass 196.

II. Claims 12 and 17, drawn to a peptide, peptidomimetic or synthetic molecule that interacts competitively or non-competitively with the active site of a FabH of claim 1 or inhibits the enzymatic activity of a FabH, classified in class 514, subclass 789.

III. Claim 18, drawn to a method for solving a crystal form of a mutant, homologue, or co-complex of FabH, classified in class 702, subclass 27.

IV. Claims 13-16 and 22-27, drawn to a method of identifying an inhibitor compound using the structural coordinates of Figure 1 and Tables I-II, classified in class 702, subclass 27.

V. Claims 13, 15, and 22-27, drawn to a method of identifying an inhibitor compound using the structural coordinates of Figure 2 and Table III, classified in class 702, subclass 27.

[7] The inventions are distinct, each from the other because:

[8] The polypeptide of group I and the interacting molecule of group II are patentably distinct for the following reasons: While the interacting molecule of Group II binds to the polypeptide of Group I, the polypeptide of group I and the interacting molecule of group II are structurally distinct molecules; any relationship between a polypeptide of group I and an interacting molecule of group II is dependent upon the correlation between the scope of the polypeptides and binding partners that would be generated using the polypeptide. In this case, the polypeptide of group I is a large molecule which contains potentially hundreds of regions to which a binding partner may bind. Thus the polypeptide of group I would result in the production of binding partners outside the

scope of group II. Therefore the polypeptide and interacting molecule are patentably distinct. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an interacting molecule each require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the interacting molecule of group II. Furthermore, interacting molecules that bind to an active site of a polypeptide of group I may be known even if a polypeptide of group I is novel.

[9] The polypeptide and crystal of Group I are unrelated to the methods of Groups III-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the polypeptide and crystal of Group I are neither made nor used by the methods of Groups III-V.

[10] The interacting molecule of Group II is unrelated to the method of Group III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the interacting molecule of Group II is neither made nor used by the method of Group III.

[11] The interacting molecule of Group II and the methods of Groups IV-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can

be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the interacting molecule of Group II can be used as an affinity reagent in the purification of the polypeptide of Group I.

[12] Inventions III, IV, and V are related as using structural coordinates of a FabH polypeptide. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each method uses structural coordinates of a different polypeptide structure. The method of Group III comprises different method steps and yields a different result as compared to the methods of Groups IV and V. Regarding the methods of Groups IV and V, the specification discloses that the structural coordinates of Figure 1 are of the E. coli FabH dimmer and the structural coordinates of Figure 2 are of the E. coli FabH monomer in complex with acetyl-CoA (specification at p. 2, bottom). Thus, the methods of Groups IV and V use different structural coordinates representing structurally distinct macromolecules.

[13] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-V are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the

examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search and thus, co-examination of the inventions of Groups I-V would require a serious burden on the examiner.

[14] Claims 13, 15, and 22-27 will be examined only to the extent the claims read on the elected subject matter.

[15] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[16] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

[17] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656